UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,780	07/07/2000	Erik Marcussen	5766.200-US	7010

25908 7590 11/27/2001

NOVOZYMES NORTH AMERICA, INC.
C/O NOVO NORDISK OF NORTH AMERICA, INC.
405 LEXINGTON AVENUE, SUITE 6400
NEW YORK, NY 10174

EXAMINER
HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
1761	8

DATE MAILED: 11/27/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/611,780	Applicant(s)	
	Examiner	Group Art Unit 1761	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 9-10-01.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) ~~1-32~~ is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 1-16 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:_____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of Group I in Paper No. 6 is acknowledged. Claims 17-32 are withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and thus dependent claims 2-16, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Although these are method claims, they rely upon the production of the cooperative relative positioning and functions of the components within the granule produced. The claims are disjointed, and thus rejected, for the following reasons:

- Claim 1 does not require the use of, nor the actual existence of, an enzyme. The preamble refers to a process of making a "dry enzyme-containing" product, but does not provide any actual components or steps relating to the enzyme.
- The phrase "mixer-granulation granule" is confusing and appears unnecessary. It is unclear if this imparts some tangible, physical difference to the granule, or if this merely denotes the manner in which the granule is made. Either way, it is noted that the claims

are directed to a method of making the granule, and specifically recite the use of a "mixer granulation process", thus eliminating the need for the phrase above.

- The phrase at lines 2-3 of claim 1 renders the claim(s) indefinite, as it is unclear as to how one skilled in the art would "add a particulate *component* to a mixer granulation *process*". A component may be added to other components or products, but within claim 1 it is unclear at what stage, and to what other component/product, the particulate is added.
- The structural and functional relationship of the "particulate component" to the remainder of the granule produced is unclear. It is unclear what function the "particulate component" possesses, and how it is related to the enzyme.
- The phrase "the particles of the particulate component" renders the claim confusing, as it was not earlier defined that the "particulate component" was composed of more than one "particulate". The term "particulate" relates to "minute separate particles", or a "particle substance" (Webster's Ninth New Collegiate Dictionary, 1983), and thus the claimed use of the phrase "the particles of the particulate component" appears to conflict with the common definition of a single "particulate component."
- It is unclear if the enzyme (when specifically present) can be the "particulate component".

Keep? claims 33-35

Claim 13 is indefinite for the confusing recitation of the Markush-type language. The claim states that the granule "comprises *one or more*... selected from the group *consisting of*... *and combinations thereof*." Initially, the term "one or more" is unnecessary in light of the subsequently-recited "combinations thereof". Secondly, the phrase "one or more" immediately follows the term "comprises", while the claim goes on to recite items which are "selected from the group consisting of" A, B, C, "and" D. It is suggested that the phrase "one or more" be deleted, such that the phrase "and combinations thereof" may more clearly refer to and define the set of granulating agents.

In claim 14, the use of the Enzyme Classification numbers ("1._._._") are unnecessary and render the claim tedious and confusing. The E.C. numbers would readily be known to one skilled in the art by the simple recitation of the name of the enzyme class (i.e. transferases, hydrolases, etc.).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Herrman et al. (WO 97/43482), submitted in the IDS.

Herrman et al. disclose the production of an enzyme granulate made by a mixer granulation process. The process comprises adding to an enzyme preparation, a cereal grain or legume flour, such as wheat, rye, soy, pea, etc., which has been treated by dry superheated steam, and ground. The enzymes listed at pages 10-11 include oxidoreductases, hydrolases, etc. As shown in claim 1 of the reference, the process "is characterized by the fact that one first prepares a wet granulate" which comprises the enzyme mixture, and "75 to 99 parts by weight (including moisture content) of an organic flour with a degree of grinding of 30 to 100%", as well as optional granulation and/or formulation agents, wherein subsequently the wet granulate "is further dried", and optionally coated. A high-shear mixing apparatus is utilized to form the granule. As shown in claim 22, the finished product, which has been dried, comprises the dried enzyme

mixture, and "96.92 to 43.8 wt. % (dry substance)" of the flour substance. As instant claim 1 states that "the particulate component comprises less than 75% of the *finished granule*", and as the reference teaches that the dried, finished granule comprises from 43.8% to 96.92% of the flour particulate component, the reference anticipates instant claims 8-12. Further, at page 13 of the reference, "granulation and formulation auxiliary agents" are listed, which "can be added in an amount up to [a] maximum of 20%" of the prepared moist granule. These agents include inorganic compounds such as silicates, kaolin, bentonite, alkali chlorides and alkali sulphates, and calcium carbonate and calcium sulphate. Whether specifically named as the intended particulate or not, these compounds would thus meet the limitations of instant claims 4-7 and 13, and constitute "less than 75% by weight of the finished granule (instant claim 1), and their mean size would be commonly available in particles of a "mean size of more than 40 μm."

Common particle size ranges and percentage distributions within flours were well-known and documented throughout the art, and such flours were known to have "a mean size of more than 40 μm" (instant claim 1). For example, common particle sizes of pasta wheat flours, which are even smaller than traditional wheat flours, are in the 550-150 micrometer granulation particle size range; some having a more standardized flour with a granule range of 350-130 micrometers (*Handbook of Cereal Science and Technology*, Lorenz et al., 1991, page 16), and corn (maize) was known to be in "the commonly used particle-size range (100-1,000 μm)" (*Influence of Particle Size on the Twin-Screw Extrusion of Corn Meal*, B. W. Garber, et al., Cereal Chem. 74(5):656-661, Copyright 1997 by the American Association of Cereal Chemists, Inc.).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached at (703) 308-3959. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3602.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

KEITH HENDRICKS
PRIMARY EXAMINER